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10/615,528	07/08/2003	Raymond E. Ideker	5656-31	8193

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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/615,528	IDEKER, RAYMOND E.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-32,36,55-67,71,72 and 91-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-32,36,55-67,71,72 and 91-107* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 July 2003 and 20 November 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on June 7, 2007. Claims 1-19, 33-35, 37-54, 68-70 and 73-90 have been cancelled. Claims 20-32, 36, 55-67, 71-72 and 91-107 are pending.

Claim Rejections - 35 USC § 112

2. In view of the response filed June 7, 2007, the 35 U.S.C. 112, first paragraph rejections applied against the claims in the Office Action of February 6, 2007 have been withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. ***Claims 20-32, 36, 55-67, 71-72 and 91-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sippensgroenewegen (U.S. 2001/0056289) in view of Narayan et al. (U.S. 7,123,954) (herein Narayan).*** As to Claims 21, 27, 36, 55-56, 62, 72, 98 and 106-107, Sippensgroenewegen expressly disclose a system and method 100 for localizing and/or treating arrhythmias of a patient's heart and thusly reducing an occurrence of fibrillation (by ablation) (see Sippensgroenewegen Abstract and Fig. 9). The method includes forming a database that comprises information (i.e. patient specific, left and right atrial P-wave integral reference maps) regarding a plurality of known arrhythmia cycles, each known arrhythmia cycle having an associated known

arrhythmogenic region, read as a known fast activating region. The patient specific, left and right atrial reference maps are generated by inducing various types of arrhythmias, using intracardiac pacing, where the various types may include, for example, paroxysmal atrial fibrillation, read as non-sustained tachycardia, persistent atrial fibrillation and/or premature atrial beats with focal atrial fibrillation (see Sippensgroenewegen Figs. 5A-C and 6A-F, pages 2-3, paragraphs 19-20 and pages 6-7, paragraphs 64-68). Once left and right atrial databases 70, 80 are established at step 100, un-classified spontaneous/intrinsic cardiac cycles of 62-channel ECG data are acquired simultaneously from each sensor 12 of array 10 at step 102 in order to create an integral map that can be compared with the databases of reference maps for subsequent classification of the measured spontaneous/intrinsic cardiac cycles (i.e. whether the spontaneous/intrinsic rhythm is classified as non-sustained tachycardia, persistent atrial fibrillation or premature atrial beats with focal atrial fibrillation). Specifically, at step 104, once a paced/induced P-wave integral reference map from either of database 70, 80 has been selected as the closest correlation to the generated map from the spontaneous/intrinsic data, an arrhythmogenic region, read as a fast activating region 106 for the now classified rhythm is localized (see Sippensgroenewegen page 2, paragraph 18, page 5, paragraph 51 and page 6, paragraphs 61-63).

Sippensgroenewegen further discloses that once fast activating region 106 is non-invasively identified by comparison step 104, it may be advantageous to invasively localize the fastest activating origin/exit site within non-invasively identified region 106 at step 108 using pace-mapping. An ectopic/focal origin, read as the starting point or the exit site, read as the ending point of a concealed accessory pathway, read as a closed pathway of the reentrant region/fast region 106 is identified at step 108 using internally implanted electrodes of a pace-mapping catheter 110 (see Sippensgroenewegen Figs. 9-10, pages 2-3, paragraphs 14-19 and page 7, paragraphs 73-75).

Sippensgroenewegen expressly discloses that pace mapping is effected by electrical stimulation of candidate ectopic origins within fast activating region 106. The electrical stimulation supplied by electrodes of a pace-mapping catheter 110 induces arrhythmias classified for region 106 to produce ectopic/paced heartbeats, which can be measured by array 10, or a similar array adapted for use in a high electromagnetic field environment. The measured ectopic/paced heartbeats of the induced arrhythmia at a candidate site are used to locate the starting point/ending point, i.e. the fastest activating region of region 106. Once the fastest activating region is determined of either non-sustained tachycardia, persistent atrial fibrillation and/or premature atrial beats with focal atrial fibrillation are located as discussed above, ablation of the fastest activating region is effected at step 109 by applying an electrical stimulus to the determined starting point/end point (i.e. the fastest activating region within non-invasively identified region 106 (see Sippensgroenewegen page 7, paragraphs 73-75). Sippensgroenewegen expressly discloses a kit, read as computer program product 120 comprising a computer readable medium having computer readable program code embodied thereon for executing the method as discussed above (see Sippensgroenewegen Fig. 10 and page 8, paragraphs 76-80). Sippensgroenewegen discloses the claimed invention as previously discussed except that it is not specified that the intracardiac pace-mapping catheter 110 record a monophasic activation potential associated with the induced ectopic/paced heartbeats emitted by the electrodes of the catheter 110.

Narayan, however, teaches that when using invasive pace mapping to localize an arrhythmia circuit or fastest activating region (see Narayan Figs. 4 and 9, columns 30-35 and column 36, lines 1-17) following a non-invasive acquisition scheme that identified a broader/larger arrhythmogenic region (see Narayan column 15, lines 10-67 and columns 16-29), monophasic action potential or unipolar intra-cardiac electrogram recordings facilitate the similarity/comparison analysis between

induced recordings /measurements and event-specific recordings/measurements. Narayan expressly discloses that the electrode of pace-mapping ROVE catheter 138 that produces the closest electrogram correlations is the electrode that is positioned closest to the arrhythmia circuit (i.e. the fastest activating region) that is to be subsequently ablated. Narayan further specifies that the intra-cardiac electrogram signals are preferably recorded in unipolar or monophasic action potential configurations in order to enable improved confirmation of electrogram shape match in the comparative analysis (see Narayn column 31, lines 12-19 and lines 50-67, column 32, lines 1-10, column 34, lines 1-5, column 35, lines 35-67 and column 36, lines 1-15). Narayan further teaches that body surface ECG recording electrodes often cannot distinguish differences between typical and atypical atrial flutter, therefore it is desirable to employ invasive pace-mapping studies that use recorded electrogram signals, as previously discussed, in order to precisely localize an arrhythmia circuit/fastest activating region within a non-invasively localized arrhythmogenic region associated either atypical or typical atrial flutter (see Narayan column 1, lines 60-67 and column 2, lines 1-66). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method, system and computer readable program code of Sippensgroenewegen in view of Narayan such that an electrode of the intracardiac pace-mapping catheter 110 records monophasic activation potentials associated with the induced ectopic/paced heartbeats emitted by the electrodes of the catheter 110 in order to provide an improved system for classifying and localizing arrhythmia that simplifies the analysis portion of the invasive arrhythmia circuit localization steps.

5. As to Claims 22, 24, 28, 30, 57, 59, 63, 65, 99 and 101, the Examiner takes the position that the concealed accessory pathway, read as the closed pathway of the reentrant region/fast activating region 106, as disclosed by Sippensgroenewegen, inherently comprise a reentrant region having a

refractory period that is less than areas adjacent to the reentrant region since this is a physiological characteristic of fibrillation mechanisms of the heart. The Examiner supplies Huang et al. (*Regional Differences in Ventricular Fibrillation in the Open-Chest Porcine Left Ventricle*. Circ. Res. 2002; 733-740) (herein Huang) as evidence for this inherency. Huang specifically discloses that a fastest activating region contains a stable reentrant circuit called a mother rotor, which has a shorter refractory period than the remainder epicardial tissue (see Huang page 733).

6. As to Claims 23, 29, 58, 64 and 100, Sippensgroenewegen inherently comprise the limitation of this claim. As known in the art, a mother rotor is synonymous with a fastest activating region's first wave front. The Examiner also takes the position that mother rotors spawn daughter rotors, which is a physiological characteristic of fibrillation mechanisms of the heart with Huang supplied as evidence. Huang specifically states that a mother rotor spawns wavefronts that propagate to maintain ventricular fibrillation elsewhere or other than the location of the fastest activating region's mother rotor (see Huang pages 733-740).

7. As to Claims 25, 31, 60, 66 and 102, as previously discussed, an ectopic/focal origin, read as the starting point or the exit site, read as the ending point of a concealed accessory pathway, read as a closed pathway of the reentrant region/fast region 106 is identified using the invasive steps of the method of Sippensgroenewegen (see Sippensgroenewegen pages 2-3, paragraphs 19-20 and page 7, paragraphs 73-75).

8. As to Claims 26, 32, 61, 67 and 103, it is inherent that the starting point and ending point are adjacent to on another since Sippensgroenewegen specifies that the pathway is a concealed accessory pathway (see Sippensgroenewegen pages 2-3, paragraphs 19-20 and page 7, paragraphs 73-75).

9. As to Claims 71 and 104-105, the previously modified Sippensgroenewegen reference does not disclose expressly that that the fastest activating region is determined by determining a refractory

period associated with the fibrillating heart using premature stimulation or that that region is determined by determining an activation recovery interval measurement associated with a fibrillating heart. Instead, as previously discussed, the previously modified Sippensgroenewegen reference records monophasic activation potentials associated with induced rhythms in order localize a fastest activating region.

At the time the invention was made, it would have been an obvious matter of design choice to one having ordinary skill in the art to localize a fastest activating region within the method taught by Sippensgroenewegen in view of Narayan by either determining a refractory period associated with a fibrillating heart using premature stimulation or by determined an activation recovery interval measurement associated with a fibrillating heart because Applicant has not disclosed that either alternative provides an advantage, is used for a particular purpose, or solves a stated problem. One or ordinary skill in the art, furthermore, would have expected the method of determining a fastest activating region as taught by Sippensgroenewegen in view of Narayan and Applicant's invention, to perform equally well with either recording monophasic activation potentials associated with induced rhythms as taught by Sippensgroenewegen in view of Narayan or the claimed determining of a refractory period associated with the fibrillating heart using premature stimulation or the claimed determining of an activation recovery interval measurement associated with a fibrillating heart because all three perform the same function of determining a fastest activating region equally well in order to accurately localize a site to ablate, pace and/or defibrillate.

Therefore, it would have been prima facie obvious to modify Sippensgroenewegen in view of Narayan to obtain the invention as specified in the claims because such modifications would have been considered a mere design consideration which fails to patentably distinguish over the prior art. Furthermore and in addition to the arguments previously presented, it would have been obvious to

one having ordinary skill in the art to modify Sippensgroenewegen in view of Narayan with steps of/means for/instructions for determining a refractory period associated with the fibrillating heart using premature stimulation or determining an activation recovery interval measurement associated with the fibrillating heart in order to determine/localize a fastest activating region of the heart since both methods are well known in the art as admitted by Applicant at page 11, lines 20-31 of Applicant's disclosure.

10. As to Claims 20 and 91-97, in addition to the arguments previously presented Sippensgroenewegen discloses the claimed invention except that it is not specified that the electrical stimulus that is applied to the fastest activating region be either a defibrillation stimulus or a pacing stimulus. Narayan, however, teaches that in addition to ablating a determined fastest activating region, pacing/defibrillating can be accomplished by placing leads close to regions of the heart determined to contain the fastest activating region (see Narayan column 3, lines 5-25). Narayan further specifies that placing a lead close to the fastest activating region (i.e. an arrhythmia circuit) makes it easier to terminate that arrhythmia by pacing or defibrillation (see Narayan column 5, lines 45-61 and column 9, lines 5-10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify/utilize the method/system of Sippensgroenewegen to place pacing/defibrillation leads adjacent to or close to regions of the heart determined to contain a fastest activating region since such a modification would improve the invention as taught by Narayan.

Response to Arguments

11. Applicant's arguments filed June 7, 2007 have been fully considered but they are not persuasive. In response to Applicant's arguments that Sippensgroenewegen does not determine a

monophasic action potential reading in determining the fastest generating region within region 106, the Examiner respectfully disagrees. As Applicant admits at pages 13-14 of the Remarks, "activation of cardiac cells results in the movement of ions across a cell membrane, which causes a transient depolarization or activation potential". Distal electrode pair of catheter 110 of Sippensgroenewegen induces the movement of ions across cell membranes of the cardiac cells adjacent the electrodes, which causes a transient depolarization or activation potential to occur. Specifically, electrodes of catheter 110 induce a desired arrhythmia by causing the cardiac cells adjacent the electrodes to depolarization or create activation potentials, which subsequently cause contraction (i.e. ectopic/paced beats). Since each sensor 12 of array 10 operates on its own channel (see Sippensgroenewegen page 5, paragraph 51), each sensor 12 monophasically senses the ectorpic/paced beats such that an associated data matrix may be generated where each point on the data matrix represents a monophasic action potential sensed by each sensor 12 (see Sippensgroenewegen page 7, paragraphs 73-74). In view of Applicant's newly submitted amendments, however, the claims are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Sippensgroenewegen in view of Narayan. Please refer to previous sections of this Office Action for these new ground(s) of rejection.

12. In response to Applicant's argument that Sippensgroenewegen teaches away from using internally implanted electrodes applied to the heart, the Examiner respectfully disagrees. As previously discussed, Sippensgroenewegen expressly discloses that the P wave signals may be measured by a thoracic array of electrical sensors 12 in order to determine an arrhythmogenic region 106. The invention of Sippensgroenewegen is specifically disclosed to allow for invasive pace mapping such that the pace mapping is limited to the predetermined arrhythmogenic region 106 such that the typically long and traumatic invasive pace mapping procedure may be shortened and

improved. Catheter 110 tip is positioned at sites of the heart using x-ray imaging (see Sippensgroenewegen Fig. 9, page 2, paragraphs 14-18 and page 7, paragraphs 72-75).

13. In response to Applicant's argument that there is no suggestion to combine the Sippensgroenewegen and Narayan references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Sippensgroenewegen expressly discloses invasive pace mapping, as previously discussed and thusly does not teach away from using internally implanted electrodes. The Examiner makes specific reference to page 7, paragraphs 73-75 of Sippensgroenewegen where electrodes of catheter 110 are discussed. Catheter 110 tip is positioned at sites of the heart using x-ray imaging in order to effect pace-mapping to determine a fastest activating region for ablation (see Sippensgroenewegen Fig. 9, page 2, paragraphs 14-18 and page 7, paragraphs 72-75). Sippensgroenewegen discloses the claimed invention as previously discussed except that it is not specified that the *intracardiac pace-mapping catheter 110 record a monophasic activation potential associated* with the induced ectopic/paced heartbeats emitted by the electrodes of the catheter 110 (emphasis added). As previously discussed, Narayan teaches that the body surface ECG recording electrodes often cannot separate typical and atypical atrial flutter from one another, therefore it is desirable to employ an invasive electrophysiologic study that uses recorded electrogram signals in order to precisely narrow in on an arrhythmia circuit within a non-invasively determined arrhythmogenic region defined by either atypical or typical atrial flutter (see Narayan column 1, lines 60-67 and column 2, lines 1-66). It would have been obvious to one having ordinary skill in the art

at the time the invention was made to modify the method, system and computer readable program code of Sippensgroenewegen in view of Narayan such that the intracardiac pace-mapping catheter 110 records monophasic activation potentials associated with the induced ectopic/paced heartbeats emitted by the electrodes of the catheter 110 in order to provide an improved system for classifying and localizing increased types of arrhythmia that simplifies the analysis portion of the invasive arrhythmia circuit localization steps.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Swanson (U.S. 6,088,614) uses invasive pace-mapping to determine the locations of reentrant VT for ablation. Groenewegen et al. (U.S. 2002/0026220) disclose methods and systems for inducing various arrhythmias in a patient for generation of a P wave reference database.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jessica L. Reidel/
Patent Examiner, Art Unit 3766
August 11, 2007

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August 15, 2007